Appl. No.: 11/021,869 Patent Art Unit: 3731 27579 (51308-00059)

Reply to Office Action of 07/09/2007

## **Amendment to the Specification:**

Please replace paragraphs [0033], [0042], [0069], [0075], and [0076], as published, with the following amended paragraphs:

[0033] The presently useful additional antimicrobial components include chemicals which derive their antimicrobial activity through a chemical or physiochemical interaction with microbes or microorganisms, such as those contaminating a contact lens. Suitable additional antimicrobial components are those generally employed in ophthalmic applications and include, but are not limited to, quaternary ammonium salts used in ophthalmic applications such as poly [dimethylimino-2-butene 1,4-divl] chloride, alpha-[4-tris (2-hydroxyethyl) ammonium]-dichloride poly[(dimethyliminio)-2-butene-1,4-diyl chloride], α-[4-[tris(2-hydroxyethyl) ammonio]-2-butenyl]-ω-[tris(2hydroxyethyl)ammoniol-dichloride (chemical registry number 75345-27-6, available under, the trademark Polyquaternium 1® from Onyx Corporation), benzalkonium halides, and biguanides, such as salts of alexidine, alexidine-free base, salts of chlorhexidine, hexamethylene biguanides and their polymers, and salts thereof, antimicrobial polypeptides, chlorine dioxide precursors, and the like and mixtures thereof. Generally, the hexamethylene biguanide polymers (PHMB), also referred to as polyaminopropyl biguanide (PAPB), have molecular weights of up to about 100,000. Such compounds are known and are disclosed in Ogunbiyi et al, U.S. Pat. No. 4,759,595, the disclosure of which is hereby incorporated in its entirety by reference herein.

The non-ionic surfactant component generally is present in an amount effective in cleaning, that is to at least facilitate removing, and preferably effective to remove, debris or deposit material from, a contact lens contacted with the surfactant containing solution. Exemplary surfactant components include, but are not limited to, Tetronic® 1307, Tetronic® 1107, Tetronic® 1304, Tetronic® 904, Pluronic® F87, and mixtures thereof.

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Test cultures of *Candida albicans*, ATCC 10231 are prepared in the conventional manner. *Candida albicans* cultures are grown on agar slants from primary frozen, lyophilized or "Culti-loop®" cultures. Three mL of sterile 0.9% saline is used to gently dislodge culture growth from the agar surface. The resulting harvest is transferred to an appropriate screw cap test tube containing glass beads and vortexed for approximately one minute. The vortexed harvest is diluted as needed with sterile 0.9% saline to prepare the culture inoculum with a concentration of 1x10e8 CFU/mL. Fifty microliters of culture inoculum is added to 10.0 mL of each test sample and control, so that the final inoculum level is in the range of 1x10e5 to 1x10e6 CFU (colony forming units) per mL of *Candida albicans*, ATCC 10231. Each sample and control tube is vortexed briefly to disperse the inoculum. Contact time intervals for testing activity against *Candida* are typically 4 or 6 hours, to conform to the intended product label instructions for contact lens soak time.

[0075] It is easily seen from the data in Table 2 that CPC, in association with a predetermined concentration of a non-ionic, poly(oxypropylene)-poly(oxyethylene) block copolymer surfactant has strong antimicrobial activity. In fact, as shown in Table 3, the effect of a non-ionic surfactant on CPC's antimicrobial activity may be seen even when the surfactant concentration is far below its critical micelle formation concentration (cmc) (cmc=200 ppm for TPGS in water).

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## TABLE 3

Ingredient	% w/w	% w/w
CPC	5 ppm	5 ppm
TPGS	40 ppm	20 ppm
Polyquaternium-1	0.75 ppm	0.75 ppm
Taurine	0.05	0.05
Propylene Glycol	0.50	0.50
TETRONIC 1307 .	0.05	0.05
EDTA, Disodium	0.01	0.01
HPMC	0.15	0.15
Sodium phosphate, dibasic, 7H <sub>2</sub> O	0.12	0.12
Sodium phosphate, monobasic, H <sub>2</sub> O	0.01	0.01
NaCl	0.55	0.55
KCI	0.14	0.14
pH 7.3		
	Log Drop	Log Drop
S.marcesens	>5.07	>5.07
S.aureus	4.72	3.74
P. aeruginosa	>4.86	>4.86
C.albicans	1.36	2.54
F.solani	2.64	3.35

[0076] As shown by the formulations and resulting log reductions shown in Tables 4 and 5, the antimicrobial activity of CPC is enhanced if selected non-ionic surfactants, for example poly(oxypropylene)-poly(oxyethylene) block copolymer, non-ionic surfactants (e.g., Tetronic® or Pluronic® non-ionic surfactants), are used. The data shown in Tables 4 and 5 illustrates that CPC at low concentrations has effective antimicrobial activity with either Pluronic® F87 or Tetronic® 1307 at a concentration range that is typically used in cleaning solutions.

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## TABLE 4

Formulation	w/v %	w/v %
CPC	2.0 ppm	2.0 ppm
PLURONIC F87	0.05	0.2
Taurine	0.05	0.05
NaCl	0.53	0.53
KCI	0.14	0.14
Boric acid	0.48	0.48
Sodium borate	0.16	0.16
Edatate Disodium	0.05	0.05
pH 7.8	·	
	Log Drop	Log Drop
S.marcescens	4.73	3.56
S.aureus	>4.89	3,16
P. aeruginosa	4.89	3.89
C.albicans	>4.40	2.61
F. solani	4.23	3.05

## TABLE 5

Formulation	#1	#2	#5
	% w/v	% w/v	% w/v
CPC	7 ppm	. 5 ppm	3 ppm
Taurine	0,05	0.05/	0.05
Propylene glycol	0.5	0.5	0.5
TETRONIC 1307	0.05	0.05	0.05
EDTA, Disodium	0.01	0.01	0.01
HPMC	0.15	0.15	0.15
Sodium phosphate, dibasic, 7H <sub>2</sub> O	0.12	0.12	0.12
Sodium phosphate, monobasic, H <sub>2</sub> O	0.01	0.01	0.01
NaCl	0.55	0.55	0.55
KCl	0.14	0.14	0.14
pH 7.3			